APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-02396/94-01

License: 25-07553-01

Licensee: St. Vincent Hospital and Health Center
P.O. Box 35200
Billings, Montana 59107

Facility Name: St. Vincent Hospital and Health Center

Inspection At: St. Vincent Hospital and Health Center (SVHHC)
Billings, Montana

Northern Rockies Cancer Center
Billings, Montana

Inspection Conducted: March 28 through April 19, 1994

Inspector: Linda L. Kasner
Senior Radiation Specialist

Approved: Charles L. Cain 6/10/94
Charles L. Cain, Acting Chief, Nuclear Materials Inspection Branch — Date

Inspection Summary

Areas Inspected: This was a special, announced inspection conducted in response to a telephonic notification of six misadministrations involving brachytherapy procedures. The inspection was focused on the misadministrations, the root causes, and contributing factors; the licensee's Quality Management (QM) program and its implementation; and the licensee's oversight of its brachytherapy program.

Results:

- Six misadministrations and one recordable event were identified by the licensee's consulting medical physicists. The misadministrations involved tumor doses that ranged from 24-30 percent greater than the prescribed tumor dose. An independent medical consultant reviewed each case and determined that the radiation dose received by each patient was within a range of doses commonly prescribed for such treatments and that no long-term adverse health effects would be expected for the patients (Sections 1 and 2).

- The root cause of the misadministrations was determined to be a failure to adequately verify the accuracy of computer-generated dose tables used as the basis for developing treatment plans for brachytherapy procedures. Contributing factors to the misadministrations included problems involving the clarity of information provided in the Theratronics users' manual for the Theraplan treatment planning system, as well as a lack of clarity in the prompts and data presented to the treatment planning system users in printed format and at the treatment planning console (Section 3).

- Although the misadministrations were associated with only one of three treatment planning systems used by the licensee's authorized user physicians, the inspection disclosed that generally, all individuals participating in brachytherapy treatments either failed to perform a verification check of computer-generated treatment plans for each patient case, or failed to perform the specific checks required by the licensee's QM program (Section 4).

- Several apparent violations were identified involving the licensee's failure to implement a QM program which met each of the objectives of 10 CFR 35.32 (Section 4).

- Apparent violations were identified involving the licensee's failure to train individuals working under the supervision of authorized users in the provisions of its QM program and a failure to require that such individuals comply with the provisions of the program (Section 4).

- An apparent violation was identified involving a failure of the Radiation Safety Officer (RSO) to investigate the above noted misadministrations. In addition, concerns were raised regarding the level of oversight provided by the RSO for the brachytherapy and QM programs (Section 5).

- Concerns were identified regarding weaknesses in communications between the RSO, authorized users, and other personnel involved in brachytherapy procedures (Sections 4 and 5).

Summary of Inspection Findings:

- Apparent violation 030-02396/9401-01 was opened: Failure to instruct individuals working under the supervision of authorized users in the provisions of the licensee's QM program (Section 4.2).

- Apparent violation 030-02396/9401-02 was opened: Failure to require individuals working under the supervision of authorized users to follow the licensee's QM program (Section 4.2).

- Apparent violation 030-02396/9401-03 was opened: Failure to include all required information in written directives prepared for brachytherapy treatments (Section 4.2).

- Apparent violation 030-02396/9401-04 was opened: Failure to establish a QM program that met the objective that each administration of radiation was in accordance with the applicable written directive (Section 4.2).

- Apparent violation 030-02396/9401-05 was opened: Failure of the licensee's radiation safety officer to investigate six misadministrations (Section 5.2).

- Apparent violation 030-02396/9401-06 was opened: Failure to include all required information in records of area surveys associated with brachytherapy treatments (Section 5.3).

- Apparent violation 030-02396/9401-07 was opened: Failure to include all required information in records of patient release surveys conducted at the conclusion of brachytherapy treatments (Section 5.3).

- Apparent violation 030-02396/9401-08 was opened: Failure to include all required information in source inventory and usage records (Section 5.3).

Attachments:

- Attachment 1 - Persons Contacted and Exit Meeting
- Attachment 2 - Quality Management Program

DETAILS

1 BACKGROUND (87100)

1.1 Initial Notification of Misadministrations

On March 22, 1994, representatives from St. Vincent Hospital and Health Center (SVHHC) and one of its consulting physics groups participated in a telephonic notification of a misadministration discovered at another local medical facility. The reported misadministration involved a gynecological brachytherapy treatment, using cesium-137 sources, which was performed in September 1993. SVHHC participated in the telephone call to the NRC Region IV office because a contributing factor to the misadministration appeared to be a discrepancy in software parameters used by a computerized treatment planning system which had been used to develop treatment plans at both SVHHC and the other facility. (A similar call was made to the NRC Operations Center on March 22, 1994.)

The misadministration was not identified by consulting physicists (for both licensees) until March 1994, during the course of a detailed review of brachytherapy treatment plans developed using a Theratronics Theraplan treatment planning system. The review was initiated by SVHHC's consulting physicists after an error was identified in a treatment plan on March 16, 1994. The consulting physicists initially reported that a new staff member had identified errors in a dose table generated by the treatment planning system during a routine treatment setup.

Following considerable review of treatment plans and data generated using the treatment planning system, the physics staff, with assistance from Theratronics, concluded that the source capsule attenuation coefficient for linear cesium-137 sources was in error for all treatment plans developed on the Theraplan treatment planning system after September 1992. Specifically, the consulting physicists reported that the source capsule attenuation coefficient used for cesium-137 after that date appeared to correspond to that of a platinum-iridium source capsule rather than the steel capsule used for cesium-137 sources owned by SVHHC and the other medical facility. By review of historical treatment data, the physicists were able to confirm that dose tables generated on the Theraplan treatment planning system prior to July 1992 appeared to be correct for treatment plans developed for use of cesium-137 sources. (There were no treatment plans developed on this system between July and October 1992.)

The licensee and its representatives noted that they had identified 11 patients who had received brachytherapy treatments in accordance with treatment plans developed using the Theraplan system, and that each of these treatments was being reviewed in detail. (Only 9 of the 11 patients were treated between October 1992 and November 1993, the period in which the software parameters were found to be erroneous.)

At the time of the initial notification, the consulting physicists were unable to determine the exact circumstances which resulted in a change in the above noted software parameters. However, sufficient investigation had been done by the consulting physicists to determine that there were some data entry formats and conventions that users of the treatment planning system were previously unaware of.

On March 23, 1994, SVHHC and the other medical facility again contacted the NRC Region IV office and the NRC Operations Center separately to provide updates to their initial telephone notifications. SVHHC reported that based upon reviews completed after the notification provided on March 22 and subsequent discussions with NRC Region IV personnel, SVHHC identified six cases in which it appeared that the calculated tumor dose for brachytherapy treatments performed in accordance with treatment plans developed using the Theraplan system differed by more than 20 percent of the prescribed tumor dose. SVHHC also noted that based upon its earlier review of cases involving treatment plans generated using the Theraplan system, SVHHC initially believed that the treatments were administered in accordance with the applicable written directives. This was due to the fact that authorized users at SVHHC routinely specified brachytherapy treatments in written directives by prescribing the source strength and exposure, or implantation, period rather than in units of absorbed radiation dose. However, upon further review of the radiation dose delivered to the tumor site(s), SVHHC determined that the tumor dose in these six cases was in excess of what the authorized users originally intended. The actual tumor doses ranged from 24-30 percent greater than the tumor doses intended by the authorized users.

Due to the potential for generic problems with software parameters used by the Theraplan system and the fact that software errors went undetected and resulted in several misadministrations at more than one facility, the NRC Region IV office elected to promptly conduct a special inspection to review these events, determine the root causes, and assess the potential for generic problems in other Theratronics systems.

1.2 Background Information Regarding SVHHC's Brachytherapy Program

Prior to 1992, few brachytherapy treatments were performed at SVHHC. Although other physicians had performed brachytherapy procedures infrequently at SVHHC for some time, SVHHC elected to expand the range of brachytherapy procedures offered to its patients at the request of a new authorized user in 1991. The expansion of services involved the purchase of cesium-137 brachytherapy sources for use in gynecological treatments. The sources were received at SVHHC in October 1991, although they were not used for treatments until June 1992.

As noted above, in 1991 a new authorized user was added to the medical staff of SVHHC and to SVHHC's NRC license. Shortly after this physician joined the staff, a second new oncologist joined the medical staff of SVHHC and formed a partnership with the aforementioned physician (these physicians are referred to as physician Group 1 hereafter). In addition to the aforementioned

physicians, another group of physicians are also named on SVHHC's NRC license as authorized users. (This group of physicians are referred to as physician Group 2 hereafter.) The latter group of physicians had been practicing at SVHHC as authorized user physicians for some time prior to 1991.

The support staffs for the two groups of physicians are independent in that physician Group 1 uses a physics staff based in Billings, Montana, for treatment planning, and physician Group 2 uses a physics staff based in Casper, Wyoming, and Bozeman, Montana, for treatment planning. In both cases, the supporting physicists were not closely involved with the radiation safety program at SVHHC. (This is discussed in further detail in Sections 4 and 5.)

The supporting physics staff for physician Group 1 had accompanied the authorized users during several brachytherapy treatments performed at SVHHC. The supporting physics staff for physician Group 2 had not accompanied authorized users from Group 2 during treatments at any time during the past 2 years. Physician Group 1 and its supporting physics staff have used a Theratronics Theraplan treatment planning system and a simulation system located near SVHHC (within 2 city blocks) for treatment planning. Physician Group 2 and its supporting physics staff have used an A.R.S. and a C.M.S. computerized treatment planning systems which are located in Casper, Wyoming, and Bozeman, Montana. Simulation radiographs for brachytherapy treatments performed by physician Group 2 had been done using portable x-ray units at SVHHC. Because of the geographic separation between SVHHC and the treatment planning systems used by physician Group 2, information needed to perform computerized treatment planning had been transmitted via facsimile to the physics staff in Casper, Wyoming. (Additional discussion regarding this practice is provided in Section 4.)

2 MISADMINISTRATIONS AND RECORDABLE EVENT: CASE REVIEW (87100)

The errors in treatment which prompted the inspection involved six misadministrations and one recordable event associated with brachytherapy treatments administered in accordance with treatment plans developed using a Theraplan treatment planning system.

Based upon recalculation of radiation doses administered to prescribed tissue volumes (tumor site) and other critical organs, SVHHC's authorized users and consulting medical physicists determined that the tumor doses for six patients ranged from 24-30 percent greater than the prescribed doses, as documented in the applicable written directives and original treatment plans. In addition to the misadministrations, a recordable event was identified during the course of the physicists' review. The recordable event involved a tumor dose that was approximately 15 percent greater than the prescribed dose specified in the written directive and treatment plan. However, this case was not associated with the software errors which contributed to the misadministrations.

Each case was reviewed by the authorized users as well as by an independent radiation oncologist to determine whether any adverse health effects were likely to occur as a result of the radiation doses received by the patients.

Both the authorized users and the independent physician reviewer determined that it was unlikely that the doses received by these patients would result in any adverse health effects beyond those which may normally be expected for this form of treatment. It should also be noted that the misadministrations were associated with gynecological treatments which involved treatment by external beam as well as by brachytherapy implants. Thus, the increased tumor doses resulting from the treatment errors were only a small percentage of the total radiation dose intended for each patient. The external beam component of these treatment combinations was delivered via use of a linear accelerator, a device which NRC does not regulate. Therefore, discussion of the radiation dose received by each patient will be limited to the brachytherapy component of each treatment.

In addition, the independent oncologist who reviewed these cases noted that overall, the authorized users associated with these cases had prescribed their treatments using radiation doses that in his view were conservative. As a result, the total radiation dose administered to the patients was within a range which is generally found acceptable according to standard medical practice.

The specific details of the above noted cases and the physicians' reviews are discussed below. Specific details regarding the root cause(s) of and factors which contributed to the misadministrations are discussed in Section 3.

2.1 Review of Treatment Parameters and Radiation Dose Received by Patients

As noted above, the errors in software parameters used by a Theratronics Theraplan treatment planning system were initially discovered on March 16, 1994, during the course of a brachytherapy treatment. Brachytherapy sources had been implanted in a patient and the physicists were performing final checks of the treatment plan when the discrepancies in computer-generated dose tables were identified. The consulting physicist who initially identified the discrepancy between the computer-generated dose tables and a manual calculation of the radiation dose for specific points (a difference of approximately 20 percent) was a relatively new employee and had not used the Theratronics treatment planning system before. In addition, this physicist used a method for performing manual checks of computer-generated dose tables and treatment plans that differed from the method that had been used by SVHHC's consultants in the past. The fact that the treatment plan was verified by a method other than that which was previously used was the principle factor which led to the identification of the software errors.

Once the errors were identified and corrected, with assistance from Theratronics, the consulting physicists determined that since there was only one data file for cesium-137 sources resident in the treatment planning system at the time, there was a high probability that other treatment plans completed for use of cesium-137 sources may have been subject to the same errors. The physicists subsequently conducted a thorough review of all brachytherapy treatments performed at SVHHC and a second hospital which had also performed brachytherapy treatments in accordance with treatment plans developed on the

Theraplan treatment planning system. A total of 12 cases were identified, dating from June 1992 to March 1994, which were associated with treatment plans developed on the Theraplan system. Only eight of these treatments were performed at SVHHC. One of the 12 was the treatment which was started on March 16 and because a corrected treatment plan was promptly completed and the written directive modified accordingly, this treatment did not involve any overdose of radiation.

The remaining 11 cases were reviewed in depth, including retrieval of simulation films and original computer data, and tumor doses were recalculated using the correct source parameters. (In addition, a new method was used to verify the accuracy of the computer-generated dose tables as discussed elsewhere in this report.) Cesium-137 source data files which had been archived were examined and through comparison of the source parameter data files, it was determined that a change in the source parameters had occurred after July 1992. (The cesium-137 source strength was specified in millicurie units in June and July 1992, and in milligram-radium-equivalent units after July 1992.) Although it appeared that the change which resulted in the use of erroneous source data occurred after July 1992, the consulting physicists recalculated the tumor dose, as well as the radiation dose for critical organs, for all 11 patients.

The table below shows the prescribed tumor dose[1] for each patient treated at SVHHC, the recalculated tumor dose and the ratio of the two.

Patient No.	Prescribed Dose	Recalculated Dose	Ratio[2]
1	3,500 cGy	4,027 cGy	1.15
2	3,500 cGy	3,667 cGy	1.05
3	4,892 cGy	6,380 cGy	1.30
4	3,000 cGy	3,722 cGy	1.24
5	3,000 cGy	3,766 cGy	1.26
6	1,087 cGy	1,320 cGy	1.21
7	2,568 cGy	3,208 cGy	1.22
8	3,500 cGy	4,333 cGy	1.24

[1] For the purposes of this table, the licensee defined the prescribed tumor dose as the initial calculated dose given the parameters specified in the written directive. The calculated tumor doses were approved by each authorized user prior to the completion of treatment, along with the full treatment plan (including isodose plot). This definition is suitable given the fact that the written directives only specified the number and strength of the sources used and the implantation period.

[2] The ratio is defined as recalculated dose/prescribed dose.

The authorized user physicians involved in these cases (physician Group 1) reviewed all revised dose data (both the revised brachytherapy component and

revised combined total dose calculations) in order to evaluate whether any adverse consequences could be expected as a result of the actual doses received by the patients. These evaluations included review of the recalculated tumor doses as well as revised calculations of the doses received by critical organs (bladder, rectum, and bowel). Both authorized users determined that the corrected radiation doses were within the range of radiation doses commonly prescribed for such treatments and that no adverse consequences beyond those normally expected for this form of treatment were anticipated.

The physicians also scheduled several of the patients who had not been seen within the previous 1-2 months, as well as those who had not been followed by the authorized users for any length of time following treatment, for a followup examination. (Because the treatments had been performed from 4 to 16 months prior to identification of the errors, the physicians had seen many of the patients on several occasions subsequent to their treatment. The physicians did not believe it necessary to re-examine each of the patients for that reason.) During the followup examinations, no symptoms or complaints were noted that were attributable to the radiation doses received by the patients.

Regardless of whether a followup examination was scheduled or performed, each of the patients was contacted either by the authorized user or by her referring physician by telephone and informed of the treatment errors. The authorized users also documented all revised radiation dose calculations in written notes which were placed in the patients' medical records and forwarded to the referring physicians during the initial segment of the inspection.

One patient was later seen again by one of the authorized users for complaints of rectal bleeding (patient Number 7). Based upon information provided by the authorized users and referring physician, this patient will receive continued followup care under her primary physician who will ensure that the oncologists remain informed of her condition as appropriate. The oncologist who prescribed the patient's treatment stated that the symptoms experienced by this patient could be related to the radiation dose administered to the patient; however, the oncologist noted that if the symptoms were due to radiation, it would likely be the result of the external beam component of the patient's treatment. At the conclusion of the inspection, there was insufficient information to verify the cause(s) of the patient's symptoms.

On March 28, 1994, an independent physician with expertise in radiation oncology reviewed each of the above noted cases. This review was requested by physician Group 1 in order to provide an independent assessment of any medical consequences that might be expected for the patients as a result of the treatment errors. The reviewer provided a written report of his conclusions to the authorized user physicians as well as to the inspector for review. In his report, the physician stated that "it is my opinion that the excess doses due to the incorrect calculations involve very modest [tissue] volumes in the patients, and are in all cases, well within the doses usual and customary to treatment of patients with the specific tumor types cared for. Thus far, no

adverse acute or late reactions have been observed and I predict none will occur."

2.2 Notification Provided to the NRC, Patients, and Referring Physicians

As discussed above, the software errors were initially discovered on March 16, 1994. Following this discovery, SVHHC's consulting medical physicists spent 2-3 days identifying which patients had been treated in accordance with treatment plans developed using the Theraplan treatment planning system and recalculating radiation doses received by the patients. SVHHC management representatives were first notified of the errors on March 21, 1994. At that time, some confusion existed regarding whether the six misadministrations should be so classified because of a minor technical dispute regarding NRC's definition of a misadministration versus the manner in which treatments were specified in written directives at SVHHC.

The issue noted above was mentioned, although not in detail, during the initial telephonic notification provided to the NRC Region IV office. During subsequent conversations with SVHHC's consulting physicists, the inspector explained the criteria used to define a misadministration relative to the manner in which a treatment is specified in a written directive. The consulting physicists reviewed the subject of these discussions with SVHHC representatives who reviewed the treatments again and determined that the six cases should be declared misadministrations. This decision prompted a second telephonic notification regarding the six misadministrations on March 23, 1994.

The authorized user physicians who prescribed these treatments notified the referring physicians by telephone of the misadministrations within 24 hours of the above noted notifications to the NRC. Subsequent to their telephone discussions with the referring physicians, the authorized users forwarded copies of their revised chart notes (which included details of the radiation dose received by each patient) to the referring physicians. SVHHC noted in its written report that the referring physicians indicated that they preferred to inform their patients of the errors. However, the authorized users informed the inspector that they had also been in contact with several of the patients and had scheduled followup visits with some of the patients as noted above.

Based upon information gathered through interviews with the authorized users and SVHHC staff, it appeared that much of the responsibility for informing the referring physicians was placed on the authorized users rather than SVHHC's radiation safety officer (RSO). In fact, as discussed in Section 5, SVHHC's RSO did not become involved in the investigation of the misadministrations; however, letters were sent to each of the referring physicians on March 23, 1994, under the RSO's signature. The letters were very general in nature and did not specify the actual dose received by the patients, but instead stated that the patients received a radiation dose in excess of the intended dose by the appropriate percentage.

A written report documenting the misadministrations, the apparent causes, and the corrective actions taken to date was submitted by SVHHC to the NRC on April 5, 1994. A major portion of the report had been prepared by SVHHC's consulting physicist. Generally, the report contained the information required under 10 CFR 35.33; however, the written report did not specify what information was provided to the patients in the initial notifications. In response to a request by the inspector, SVHHC did submit a portion of a copy of one of the written reports provided to a patient for the inspector's review. The report provided to the patient did indicate that a copy of the written report submitted to the NRC was attached.

As referenced above, SVHHC relied upon the authorized users and the consulting physicists to investigate the misadministrations and to provide information relative to the investigation to SVHHC management representatives. Based upon discussions with other physicists who provide consulting services to SVHHC, SVHHC personnel, and the physicians and physicists involved in the misadministrations and the ensuing investigation, there appeared to be some difference of opinion on several factors. The most notable difference involved discussion of whether the six cases should be classified as misadministrations.

In several discussions, one consulting physicist who was not involved in the six treatments raised questions regarding whether the application of additional attenuation factors in the revised dose calculations would reduce the revised doses to levels below the threshold specified in NRC regulations for a misadministration. In addition, in its written report, SVHHC stated that the six reported cases "may not precisely meet the technical definition of a misadministration." The report noted that based upon the definition of a misadministration and prescribed dose provided in 10 CFR 35.2, that the patients did receive the dose specified in the written directives. This statement was predicated on the fact that SVHHC's written directives require that the authorized users specify the treatment dose in terms of source strength (milligram-radium-equivalent) and implantation period (hours), and that in the six cases there was no deviation from those two factors. (It should be noted, however, that the source strengths specified in the written directives prepared by SVHHC's authorized users did not specifically match the actual activity content of the sources in SVHHC's possession. The authorized users had instead noted only a nominal source strength.)

SVHHC's written report also noted that the "calculated administered dose" is not defined in NRC regulations, although the report confirms that the calculated doses identified in the report were the actual doses received by the patients. The report further stated "the difficulty in these cases is that errors occurred in arriving at the prescribed dose..." and "regardless of whether these cases involve misadministrations, the patients received more than the treating physician and the treatment planning team would have intended had they had the correct data from the Theraplan L system."

These issues were discussed in detail with the authorized users who prescribed the subject treatments. The authorized users stated that they preferred to

prescribe treatment doses in terms of absorbed dose; however, they were mandated by SVHHC's Quality Management (QM) program to specify the dose in written directives as described above. The authorized users also noted that in their view, the prescribed treatment dose was the absorbed dose as calculated in the final treatment plan, and the doses administered to the six patients did exceed what they had intended, by a margin of 24-30 percent. Thus, the authorized users stated that they believed that the cases did constitute misadministrations.

Although the inspector discussed the issues described above in detail with both SVHHC management representatives and the authorized users, the differences in opinions were not resolved during the course of the inspection as evidenced by the licensee's written report.

In summary, six cases were identified through the licensee's consultants' and authorized users' investigation which appear to meet the criteria for misadministrations in that the tumor dose received by the patients exceeded the dose intended by the prescribing authorized user by 24-30 percent. However, based upon reviews conducted by the authorized users and an independent radiation oncologist, it does not appear that the misadministrations will result in any adverse health effects beyond those which may normally be expected for this form of treatment. The licensee reported the events to NRC as required and the appropriate referring physicians were notified of the errors in writing. SVHHC relied upon the referring physicians to notify the patients; however, the authorized users also discussed the treatment errors with some of the patients and performed followup examinations for those patients which they deemed necessary. Written reports of the misadministrations were provided to both the NRC and affected patients as required by 10 CFR 35.33.

In addition to providing required reports to the NRC, patients, and referring physicians, the licensee's consulting physicists submitted a report regarding the apparent software problems to the Food and Drug Administration (FDA) in accordance with FDA's MEDWATCH program.

The licensee and its representatives were informed during the inspection that NRC plans to have a medical consultant review each of the misadministrations and provide an assessment of any potential consequences, both short- and long-term, resulting from the radiation doses received by the patients.

3 ROOT CAUSES AND CONTRIBUTING FACTORS (87100)

The inspector's review of the misadministrations included: (1) detailed examination of the Theraplan system formats for data entry and the procedures used for independent verification of treatment plans and dose calculations by the consulting physicists working with physician Group 1, (2) interviews with representatives of the manufacturer of the treatment planning system, and (3) review of supporting documentation provided by the manufacturer for system users. In addition, the inspector conducted a review of safety bulletins issued by the manufacturer in accordance with requirements of the FDA in order

to assess whether any incidents related to factors associated with the misadministrations had been previously identified to system users. No user safety bulletins were identified involving the specific issues associated with the six misadministrations.

The root cause of the misadministrations was determined to be the method used to perform independent (manual) checks of computer-generated treatment plans and dose tables. Specifically, the published dose tables used by individuals performing treatment plan verification checks were inappropriate for use with the cesium-137 sources used for brachytherapy treatments at SVHHC. The contributing factors identified during the inspector's review included a lack of clarity in instructions related to data input provided in the Theraplan users' manual and in prompts and data presented to system users in printed format and at the treatment planning console. In addition, another contributing factor was the users' failure to implement a rigorous system of controls for data entry and system use. These issues are discussed in detail in the following paragraphs.

3.1 Root Cause of the Misadministrations

The initial discovery of the errors in the cesium-137 source data file occurred during an independent (manual) verification of a treatment plan on March 16, 1994. It should be noted that although SVHHC's QM program does not require this specific type of verification, the consulting physics group working with physician Group 1 had routinely performed manual dose calculations (using "along and away" tables) for one or more points for each patient case. On March 16, the individual performing the independent check used a different set of along and away tables than those which had been used in the past. The manual dose calculations differed from the computer-generated dose calculations by approximately 20 percent, which prompted further investigation by the consulting physicists.

The independent verification check performed on March 16 was conducted using along and away tables developed by E. H. Quimby, et. al., which were published in Physical Foundations of Radiology, Fourth Edition. (The Quimby tables are a system of dose tables which allow a user to determine an expected dose rate value at a certain distance from a radium-226 source of given strength or other source specified in milligram-radium-equivalent. The tables contain dose rate data for radium-226 encapsulated in both 0.5 mm and 1.0 mm of platinum.) The physicist who performed the check on March 16 used the Quimby table corresponding to a source encapsulated in 0.5 mm of platinum.

After the initial discrepancy was identified, the consulting physicist who performed the verification check conducted a second check to verify the accuracy of the computer-generated dose tables. This was done by entering data for a single source with known coordinates and generating a dose table which was then compared to a second published dose table. The published dose table used for comparison during this check was a dose rate table developed for cesium-137 sources encapsulated in 1.0 mm of stainless steel. The data was developed by V. Krishnaswamy, as published in Radiology, Vol. 105:181-184,

1972 and later reproduced in other textbooks. The second comparison also revealed a significant difference (greater than 20 percent) between the computer-generated dose tables and the manual dose calculations.

Following the second check, technical representatives from Theratronics were consulted for assistance. Theratronics representatives were able to provide the consulting physicists with a set of cesium-137 source parameters which had been used at other medical facilities so that the resident source data file could be replaced with appropriate data. The new parameters were entered and a check was run using the Krishnaswamy tables in order to verify the accuracy of dose calculations performed using the new parameters. The computer-generated dose tables from this check corresponded well with independent checks performed using the Krishnaswamy tables (values were within 1.5 percent). The new source data parameters were used to develop a revised treatment plan for the brachytherapy treatment which was ongoing at that time. Dose tables for the particular combination of sources used on March 16 were recalculated and the implantation period was modified accordingly in order to deliver the authorized user's intended tumor dose.

Once acceptable source data parameters were established and entered in the appropriate software files, the consulting physicists sought to identify the root causes of the errors. Their initial investigation identified several facts which were later confirmed and supplemented during the inspector's review. The physicists' first finding was an obvious difference between the cesium-137 source data files resident in the treatment planning system and those provided by Theratronics. The source data parameters resident in the system and those provided by Theratronics are shown below. (These parameters are entered in a data file which is accessed by programs used to calculate dose tables for any given source combination.)

Source Parameter	Resident Data	Data Provided by Theratronics
*Source Type:	137-Cs	137-Cs
*Total Length:	2.00 cm	2.00 cm
*Active Length:	1.5 cm	1.5 cm
Gamma Constant:	8.25 R/mgm•hr	8.39 R/mgm•hr
Rad/Roentgen:	0.940	0.957
*Wall Filtration:	0.930 mm	0.930 mm
Filter Atten. Coeff:	0.000	0.221
*Half Life:	262980 hrs	262980 hrs
*Active Diameter:	0.124	0.1
Source Atten. Coeff:	0.081	0.081

* No changes were recommended for these items because they are physical characteristics defined by the manufacturer.

Based upon comparison of the two sets of data, the consulting physicists determined that the filter attenuation coefficient value was the major contributor to the differences in the calculated dose values. The physicists

attempted to investigate this issue further and in doing so, retrieved some archived source data parameter tables that had been used with earlier versions of the software system. In reviewing the older data files, the physicists noted that the filter attenuation coefficient used prior to September 1992 did not appear as 0.000 in records of the data tables. Licensee representatives initially identified the discrepancy in the filter attenuation coefficient value as the primary cause of the misadministrations.

Although the discrepancy in the filter attenuation coefficient entered in the source data file was identified by the inspector as a contributing factor which led to the misadministrations, it was not determined to be the root cause of the misadministrations. As discussed in Section 3.2, several other factors were identified which also appeared to have contributed to these events.

The inspector identified an error associated with the treatment planning verification process as the root cause of the misadministrations. This error involved the use of inappropriate along and away tables in performing independent checks of computer-generated dose tables. Had the independent (manual) treatment plan verification checks been performed correctly, the errors in the computer-generated dose tables should have been discovered. The basis for determining that the use of inappropriate dose tables in performing verification checks of treatment plans was the root cause of the misadministrations is explained below.

The algorithms used by the Theraplan treatment planning system calculate the radiation dose rate at any number of points based upon information entered from simulation radiographs and data which describes the characteristics of the specific sources used for any given treatment. The process used to complete these calculations is based upon optimizing the data input at the computer terminal, which is limited in many cases to two dimensions, to represent a three dimensional model of the dose distribution in a patient. The process requires that certain values be adjusted, in an iterative fashion, in order to approximate the actual dose distribution in a three dimensional figure. In order to verify the accuracy of the computer-generated treatment plans, the calculated dose rates are compared to measured data. Generally, this is accomplished by comparing computer-generated dose tables to a set of measured data and adjusting for source strength and geometry. There are several dose tables that have been published in various journals and textbooks which may be used to verify computer-generated dose tables. In addition, there are several methods used to perform such comparisons.

In this particular case, the routine practice involved the use of dose tables developed by Quimby (referenced above). As noted above, this verification check was typically done for each treatment plan. This practice involved some error because the user was required to perform the comparison using clinical data involving combinations of sources rather than comparing the calculated dose rate for a single source to the Quimby tables. (The error involved the users' ability to accurately localize the sources in simulation radiographs in order to manually calculate the dose rate at a given point using the Quimby

table.) In addition, the source localization process also involved some error in digitization (the process used to transfer information from a radiograph to a computer file). SVHHC's consulting physicists were aware of the potential for errors in this method and attempted to take them into account in comparing the calculated and measured dose tables. However, the users failed to recognize an error involving the selection and use of the wrong Quimby table when they performed the verification checks.

Specifically, the treatment planning system users had entered data to characterize the sources in terms of milligram-radium-equivalent and accordingly, they entered a gamma constant that corresponded to the radium equivalent as filtered by 0.5 mm of platinum. (Data entered in the source data file corresponded to information provided by the source manufacturer.) However, when the independent source checks were performed, the dose tables used to conduct the checks corresponded to dose rates for a radium-226 source as filtered by 1.0 mm of platinum. Thus, the dose rates used for comparison were approximately 10 percent lower than what would have been expected for the cesium-137 sources used for treatments. This error resulted in a failure to detect the fact that the computer-generated dose table values were approximately 20 percent lower than they should have been for the specific sources used because an erroneous value had been entered for the filter attenuation coefficient. This problem was further compounded by the fact that manual checks were performed using clinical data which consisted of a combination of sources rather than with a single source for which precise source coordinates were known. The individual who routinely performed verification checks stated that the variance between the computer-generated dose tables and the Quimby table values was generally on the order of 5 percent and in the majority of cases, was less than 10 percent. Thus, the user had assumed that the computer-generated dose tables were correct and had attributed the variance to errors in digitizing information from radiographs and other factors related to determining the source location from simulation films.

In discussions focused on determining why the wrong dose tables were selected and why the error was not identified earlier, the system users explained that the error in selecting the wrong dose table for comparison was primarily linked to the former experience of the individual who had performed the majority of the verification checks. The individual explained that his former experience in brachytherapy had involved the use of radium-226 "tubes" which were encapsulated in 1.0 mm of platinum. Thus, he had naturally selected the tables corresponding to a 1.0 mm platinum filter. The error was not identified earlier because only one individual typically reviewed and approved the treatment plans due to a lack of other staff experienced in this task.

In summary, had an appropriate set of measured data been used for comparison with the computer-generated dose tables, the errors in the computer-generated dose tables should have been identified. In addition, the fact that the calculated dose tables were erroneous was of lesser significance because it is expected that some variance will exist between the calculated dose tables and the measured dose tables, and that the source parameters will have to be

adjusted in an iterative fashion in order to optimize the calculated dose tables such that they match measured data. Thus, the use of appropriate dose tables was fundamental to ensuring that (1) the algorithm used to generate calculated dose tables provided accurate data and (2) errors which may have occurred in data entry were identified.

3.2 Contributing Factors

As noted in Section 3.1, several factors were identified which appeared to have contributed to the misadministrations. Some of these factors were more significant than others; therefore, only those that merit further consideration as SVHHC develops corrective actions or considers modifications to its QM program are discussed in the following subsections.

3.2.1 Clarity of Information Provided to Theraplan System Users Regarding Data Entry Formats

Based upon discussions with the system users and Theratronics representatives, as well as the inspector's review of system prompts and data displayed at the system console and in printed format, concerns were identified regarding a lack of clarity in instructions found in the user's manual and in system prompts provided at the treatment planning console. In addition, some of the data appeared misleading to both the users and the inspector.

First, as noted in Section 2, when the errors were initially identified, the users examined the cesium-137 source data table and found that the value for the filter attenuation coefficient was displayed as "0.000". As they reviewed this data to determine the source of the errors, one of the physicists noted that a message, "RETURN for radium," was displayed as the system prompted the users for entry of a filter attenuation coefficient value. The users assumed that some default value was used if the user hit the "return" key in response to the prompt, and that the unknown default value probably corresponded to a platinum-iridium filter (material commonly used for radium-226 source capsules). However, the physicists noted that the only value that was displayed if they hit the "return" key was "0.000". Likewise, if the physicists entered the value "0" in response to the prompt, "0.000" was displayed at the terminal. In order to test their suspicion that perhaps the "return" key resulted in use of the same value as a "0" entry, dose tables were generated using both values and were found to be the same. After some review, the physicist who originally entered the source data parameters determined that he had entered a value of "0" and had assumed that this value was used as a valid entry based upon information displayed to him at the system console and in printed format.

The system users stated that they were not previously aware of any default value for the filter attenuation coefficient. Based upon discussions regarding practices related to loading software updates and data entry, it appeared that this was likely the case since the users had relied upon use of a utility file for updating the source data files when new versions of software were loaded on the system rather than entering the source data

manually. Thus, the system users had not observed the note displayed at the treatment planning console for some period of time (possibly for years) nor had they noted it in the users' manual.

The findings noted above were reviewed further during the course of the inspection. This included a thorough review of instructions provided in the system users' manual, discussions with Theratronics representatives, review of information subsequently provided by the manufacturer which was not available in the users' manual, and investigation of data entry and screen prompts using the treatment planning system. The inspector's findings are discussed below.

Discussion of general data entry formats for both the external beam software and the brachytherapy software is provided in Section 3.5 of the users' manual. This section describes system conventions for entering numeric data as single integer values and fractional values, as well as for string data. In addition, the section describes formats for default values and states, in part, that default options are "usually enclosed in square brackets" and that "default options are obtained by pressing RETURN only." Further, the text goes on to state, "in some cases, zero is a legal entry, but we wish to offer a default; in these cases, the default is obtained by pressing RETURN, and the value 0 is obtained by entering any character (the program generally will request 'Z', but any character will do) followed by RETURN."

Section 5.2.2, "Input/Edit of Linear Source Data," describes the conventions and formats for entering data to characterize linear sources. This section displays a table which briefly describes each parameter required for characterizing a linear source. The manual does contain a note under the description of the filter attenuation coefficient parameter. The note states "as radium has a complex emission spectrum of gamma rays, its transmission does not vary exponentially with filter thickness. The coefficient is a function of filter thickness, and this function may be selected in the program by pressing the return key." Based upon discussions with Theratronics representatives, it appears that the default consists of a string of data used by a polynomial function to calculate, in an iterative fashion, attenuation of the various gamma energies emitted from a radium-226 source.

Section 5.2.2, "Input/Edit of Linear Source Data," also provides some instruction regarding the fact that source characterization information for cesium-137 sources may be entered by more than one method and that in some cases adjustment of the source data parameters will be necessary in order to optimize calculated dose tables so that they match measured data. Specifically, a note under the section which describes data input for cesium-137 sources states: "a cesium linear source can be entered in one of two different ways. First, it can be entered in a manner equivalent to a radium source of specific filtration (i.e., 0.5 mm platinum). This assumes that the dose rate distribution for the source is identical to that of a radium source. This is an assumption, and the gamma constant (or exposure rate constant) will have to be adjusted to make the dose rate value at a point 1 cm from the source bisector to be the same as that for radium." The text continues with "if you wish to enter the cesium source as (a) radium

equivalent, but using the actual wall filtration and attenuation coefficient, then you will also have to adjust the exposure rate constant. This will have to be adjusted so that the dose rate at 1 cm, (as) calculated by the program, agrees with the manufacturers' specifications."

One discrepancy was identified in instructions provided to the users for entering data for the gamma constant. The instructions in Section 5.2.2 focus the user on the fact that the gamma constant will have to be adjusted under certain circumstances. This would appear to indicate to the user that the specific value used for the gamma constant is of lesser concern because it will be modified in order to obtain a calculated dose rate that matches measured data. However, a note in the source parameter data entry section clearly states that the gamma constant should be entered for an "unscreened" source. Theratronics representatives noted that the software algorithm assumes that this parameter must be defined for an unfiltered source and that the filter attenuation coefficient must be entered as a value other than "0". This rationale is not explained to the user and appears to be confusing given the fact that users are specifically instructed to modify the gamma constant value in order to optimize the calculated dose tables. The fact that "0" will not be accepted as a valid entry for the filter attenuation coefficient is also not explained in the users' manual. (The system users in this case elected to enter a screened gamma constant value, because that is the value supplied by the manufacturer, and accordingly, elected to use a filter attenuation coefficient value of 0.)

Theratronics representatives also stated that the note under the description of the filter attenuation coefficient provided in Section 5.2.2 of the users' manual was sufficient to instruct users that a default function existed for this parameter. However, the text did not specifically state that a default function will be invoked if a keyboard entry other than "return", such as "0", is used. A review of the users' manual failed to identify any clear instruction in either Sections 3.5 or 5.2.2 which explained that a keyboard entry of "0" would invoke use of a default value. In Section 3.5, the users' manual states "in many cases, a zero (0) or a one (1) response is required. To speed up the process, the option which is felt to be the most common response has been assigned the value zero (0), so that a (return) will suffice." This was the only indication identified in the above noted sections that a relationship between the keyboard entry of "0" or "return" existed.

In fact, the software does handle both entries in a similar fashion in that the entry of either "0" or "return" will result in use of a default value in those instances where a default value exists. Although users are not specifically alerted to this in the user's manual, recognition of both keyboard entries in a similar manner is due to the fact that the software is written in the Fortran language. Because of the manner in which Fortran handles data entry, if a default value exists in the Theraplan system, entry of either a "0" or "return" will result in use of the default value.

In addition to the items discussed above, another concern regarding clarity of instruction provided to system users was identified. Instructions provided in the users' manual, as noted above and elsewhere in the manual, appeared to indicate that in cases where a default value exists, entry of the numeric value "0" should be done using the character "z" or any other alpha character. Through several attempts, the inspector and users discovered that no character would actually result in use of the numeric value "0" for the filter attenuation coefficient. This appeared to indicate that the software programmers apparently did not consider this to be a valid entry. This was discussed with Theratronics representatives who noted that the use of a zero value for the filter attenuation coefficient was inappropriate. However, based upon the type of source used for a given treatment and the users' preference for adjusting source data parameters to obtain optimized dose tables, there may be some disagreement among users regarding this issue. In fact, one of the users involved in this case stated that he had intended to use the value "0" for the filter attenuation coefficient because the gamma constant entered in the source data table accounted for an equivalent attenuation of 0.5 mm of platinum. This user also noted that given the data displayed at the system console and in printed format, he thought that the system had accepted his entry of "0".

Based on the findings discussed above, three issues involving clarity of information provided in the system users' manual and in prompts provided at the treatment planning console were noted as contributing factors to the errors which resulted in the six misadministrations. The first issue involved the fact that a default value exists which is not identified to the user on the system console in the same manner as described in the users' manual (e.g., in brackets) and the users' manual does not clearly explain that entering "0" for the filter attenuation coefficient will invoke use of the default value for radium-226. Notwithstanding the statements provided in Section 3.5 of the manual, there is no clear indication to system users that in cases where a default value exists, entering a "0" will invoke use of the default value. The second issue involved the fact that the system displayed the value "0.000" which may mislead a user who intends to enter the numeric value "0" for this specific parameter. Based upon the information displayed to him/her, the user could naturally assume that the "0" has been accepted as a valid numeric entry. The third issue involved the fact that the users' manual does not inform the users that the numeric value of zero is not a valid entry for the filter attenuation coefficient parameter.

3.2.2 Data Entry and Software System Controls

In addition to the issues discussed above, other factors related to controls established for system software maintenance and usage were also identified as contributing factors. In reviewing the management of computer systems at SVHHC's consultants' facilities, the inspector identified several weaknesses and areas which warrant additional attention. Specifically, routine backup of data and re-entry of data files needs to be formalized. One example of problems associated with software management appeared to have contributed to the misadministrations as discussed below.

Although users of the Theraplan system had updated the system on several occasions and had experienced few problems in the past, the users had not developed a formal process or procedures for updating software files or for re-entering data files when required. Potential effects of this oversight were somewhat limited because software updates were primarily done by one individual. However, several individuals had performed software update tasks on various occasions. Because several individuals use the system, the inspector noted that the users may need to develop procedures or guidance for the various individuals using the system in order to ensure that standard data formats are adhered to and that the integrity of data used by various software programs is maintained.

Generally, the Theraplan users had followed the manufacturer's recommendations for loading new versions of the software system when they became available. This included the use of utility files to upload older versions of source data files into the new software in order to maintain consistency and to relieve the users of the requirement to re-enter data manually. In addition, the users had followed good practice by maintaining backup files of older versions of software, as well as each new version received from the manufacturer. However, there was no apparent formal method for cataloging the software and some information could not be retrieved from older data files during the inspection. Notwithstanding the fact that some standard practices had been developed and implemented to control data input, efforts to adhere to good software system management practices failed on at least one occasion and contributed to the misadministrations. This failure is described below. In addition, there were other instances identified in which data formats had been modified for no apparent reason (according to the system users).

According to the Theraplan users, as they were preparing for a brachytherapy treatment in September 1992, they noted that the cesium-137 data file had been deleted from the system. The users were unable to determine how the file was deleted, although some of the users did recall that they had had several problems with the system during that period. The users speculated that perhaps the system problems may have required them to reload the software system in its entirety. If that was the case, it is possible that the users simply uploaded a backup version of the software and failed to use the utility file to upload backup copies of the linear source data files. This would have had the same effect as deleting the cesium-137 source data file. (The data for cesium-137 sources is not provided by the manufacturer with each software update and must instead be reloaded from backup files or entered manually.)

Once the source data file was identified as missing, a user elected to manually enter the data and failed to review data used on previous versions for the cesium-137 source parameters. Had the user consulted data files which had been archived from earlier versions of the software, either from backup tapes or printed format, he might have identified the fact that the filter attenuation coefficient did not appear as "0.000" and could have caught the error before it affected any patient treatment plans. In addition, as noted above, the users had routinely used a utility file to reload the source data files in recent system updates and had not manually entered the data for some

period of time. The fact that data for this specific file was entered infrequently increased the potential for errors in manual data entry. The inspector also noted that had the manufacturer included cesium-137 source data in the group of resident source data files provided with the software, the potential for errors in data entry would have been sharply reduced. Although Theratronics provided source data files for nine different linear sources, data for cesium-137 sources was not included in the system software.

In addition to the error in re-entering data for the cesium-137 source parameters, other factors related to software system management were also identified as weaknesses, although they were not specifically related to the misadministrations. These included the fact that the users had partitioned the system to run on two workstations and had copied files from one workstation to the other without requirements to verify that files which were transferred in this method were current or accurate. In addition, although a log was maintained to document problems with the system, there was no formal requirement to do so and entries in the log were sporadic. As a result, it was impossible to determine why the cesium-137 source files were found missing in September 1992.

The inspector noted that the issues discussed above should be reviewed further by system users in order to develop controls and procedures over software system maintenance.

The inspector also noted other errors in data entry for the cesium-137 source parameters which indicate that checks for correct data entry may be warranted. Specifically, the active length of the sources was entered as 1.5 cm rather than 1.38 cm as indicated in the source description sheets provided by the manufacturer. Also, the gamma constant for the cesium-137 sources was entered as 8.25 R/mgm•hr, which corresponds to the exposure rate expected for a radium-226 source with 0.5 mm of platinum filtration, rather than for an unfiltered source as noted in the manual. The user entered this value for the gamma constant because he intended to enter data for cesium-137 in radium-226 equivalent values as specified by the manufacturer; however, this contributed to his entry of "0" as the filter attenuation coefficient.

3.2.3 Corrective Actions Taken for Computer Computerized Treatment Planning Systems

During the course of the inspection, the physicists working with physician Group 1 proposed and implemented corrective actions for future brachytherapy treatment planning activities with the Theraplan treatment planning system. As noted in Section 4, other issues were identified involving treatment planning processes observed in all treatment planning systems used by SVHHC; however, at the conclusion of the inspection, SVHHC had not yet reviewed these issues nor had it proposed corrective actions. The actions described below are those proposed by the consulting physicists.

As discussed in Section 3, the Theraplan users corrected the erroneous source parameter data promptly after their discovery of errors in computer-generated dose tables. In addition, the physicists reviewed the methods previously used to verify computer-generated dose tables and have proposed modifications to the existing practices. Specifically, the users indicated that they plan to generate a dose table for a single source of known coordinates and perform a comparison of the calculated dose rates with Krishnaswamy tables prior to generating the patient-specific treatment plan for each brachytherapy case in the future. This check will essentially allow the users to verify the accuracy of calculated dose tables while eliminating the uncertainties that existed in the former method. The users also noted that they plan to implement checks to detect data input errors because errors were discovered in few cases during the course of their review of all brachytherapy cases performed during the previous 2 years. (It should be noted that the latter errors did not result in misadministrations.) Finally, the review of final treatment plans will be given greater attention so that users may improve their ability to identify errors in treatment plans and ensure that records of treatments are maintained as required by internal procedures. The fact that the staff available to perform such reviews has been increased should assist the consulting staff in achieving these goals.

The latter action should prevent future occurrences similar to the recordable event identified during the consultants' review. Specifically, there was one case identified in which the source loading was changed after the original treatment plan was completed. According to the dosimetry staff, a second treatment plan was developed and approved; however, it was later discarded. Thus, the authorized users and physicists were unable to resolve the discrepancies between the written directive and treatment plan and declared the case to be a recordable event. (The difference between the tumor dose which would have been delivered according to the written directive and the dose documented in the treatment plan was approximately 15 percent.)

4 QUALITY MANAGEMENT PROGRAM (87100)

4.1 Scope of SVHHC's Brachytherapy Program

As noted in Section 1, SVHHC has two independent groups of authorized user physicians who perform brachytherapy treatments at its facility. Physician Group 1 uses a computerized treatment planning system located in Billings, Montana, and a support staff which includes two board certified medical physicists and several dosimetrists. Physician Group 2 uses two computerized treatment planning systems, one located in Casper, Wyoming, and a second located in Bozeman, Montana. Physician Group 2 is supported by a staff of two board certified medical physicists and an unknown number of dosimetrists. Since NRC's Quality Management Rule became effective (January 1992), SVHHC has performed approximately 14 brachytherapy treatments involving temporary implants of either iridium-192 or cesium-137 sealed sources. In addition, SVHHC's authorized users have also performed treatments using permanent brachytherapy implants of iodine-125 seeds.

4.2 SVHHC's Quality Management (QM) Program

By letter dated January 20, 1992, SVHHC submitted a QM program to NRC in accordance with 10 CFR 35.32. The program was developed by a consulting physicist who provides a variety of services to SVHHC although this consultant is not actively involved in SVHHC's brachytherapy program. The program was initially reviewed by members of the RSC, although the authorized users who perform brachytherapy treatments at SVHHC stated that they had not been afforded much of an opportunity to provide comments on the program or to assist in its development. The consultant who developed the program noted that copies of the program had been distributed to each authorized user and that he had not received any comments from the physicians. During the course of interviews with SVHHC staff members and the authorized users, several individuals noted that two of the authorized users had provided comments regarding the program. Those comments were focused on the redundancy of certain forms required under the program and the fact that two of the authorized users did not like the manner in which treatments were to be specified in written directives. The authorized users apparently preferred to specify treatments by absorbed dose rather than source strength and exposure (implantation) period. However, no action had been taken in response to the authorized users' comments.

The highlights of the program developed for brachytherapy are summarized below:

- Treatment Planning Computers

  The program requires that any digital or manual computer used for calculating radiation dose rates must be tested for accuracy. The test must include calculation of the dose rate from single sources at several distances as well as the dose rate from source combinations to determine if the summation of dose rates is performed correctly.

  The program does not specify how the computer users are to perform the accuracy checks, the frequency at which such checks must be performed, or who is to review the checks and how they are to be documented.

- Verification of Patient Identity

  Section 1 of Form B of the licensee's QM program requires that a technologist or authorized user provide written verification that the patient's identity has been confirmed by asking the patient his/her name and by a second method. The program does not specify what constitutes a secondary method, nor were procedures developed to inform individuals of how they should meet this objective.

- QM Program Reviews

  The program specifies that a review of the effectiveness of the QM program will be conducted at every RSC meeting and that the reviews will consist of, but not be limited to, a review of all records of implants performed during the previous (calendar) quarter. The program specifies that the review will focus on completeness and consistency of records.

- QM Forms

  Three forms are specified for use in the program: (1) Form A, "Directive for the Administration of Brachytherapy Isotopes;" (2) Form B, which includes sections on patient verification, radioactive material verification, and source loading; and (3) Form C, "Dose Calculations Check." The form for the written directive requires only that the activity of the sources be specified and that the total number of sources for a tandem or ovoid applicator be specified. Units of "mg" are shown on the form but the form does not specify whether source strength is to be specified as a radium-226 equivalent; however, users of the form have understood that source strength is to be specified as milligram-radium-equivalent. Of interest was the fact that Form A appears to have been intended for use as a written directive but it does not contain all information required by 10 CFR 35.32 even when completed. Section 3 of Form B, "Loading," specifies the information required in a written directive. This section of the form requires that the authorized user specify the number of sources, the individual and total source strengths, and the treatment time. Neither Form A nor Form B required that the authorized user specify the treatment site.

  Form C specifies two types of checks required to verify that data entered in and generated by computerized treatment planning systems is correct. The first check is to include written verification of the source data (number and strength) entered for computer calculations against information specified in the written directive. The second check was intended to verify that source localization was accurate in the treatment plan and required that user perform a direct comparison of the source position during simulation and the positions used in treatment planning by overlay of the simulation radiographs and the computer-derived isodose plots. The program specifies that a 2 mm deviation between the position indicated by the isodose plot and the position of the opacity representing the dummy sources (as viewed in simulation radiographs) will be found acceptable. The program did not require users to verify or perform independent checks for each treatment in order to ensure that calculated dose rates used to determine the exposure (implantation) time were accurate.

Following SVHHC's implementation of the QM program, the chief nuclear medicine technologist provided training in the provisions of the program to his staff, and both the chief technologist and the consultant who developed the program

provided some level of instruction to members of the nursing staff who routinely cared for patients undergoing brachytherapy treatments. The latter training was limited to the extent that the nurses performed any function covered by the program and was provided concurrently with annual refresher training on radiation safety and brachytherapy in general.

Based upon discussions with nursing personnel, it appeared that the scope of instruction provided to the nursing staff was generally sufficient for the duties assigned to them. However, the inspector discussed concerns with licensee staff regarding a standardized form used to document physician orders for the staff. The form, which was routinely placed in the patient's chart, required that the nursing staff call the responsible authorized user 1 hour prior to the scheduled termination of a brachytherapy treatment to remind the user of the need to be present to remove the applicator and sources. Through interviews with the authorized users, the inspector found that physician Group 2 had relied upon this notification while physician Group 1 had not. This was noted as a concern because based upon a review of patient charts, the inspector determined that there often was not enough information documented in the chart for the nursing staff to accurately determine when brachytherapy sources should be removed. In addition, the nursing staff had not been trained in how to interpret the written directive or QM forms which were often the only documents noting the treatment period. A second issue involving this form was also identified. The form included specific instructions for the (nursing) staff to retrieve brachytherapy sources and place them in a portable lead safe if sources became dislodged during treatment. Although the nursing and technical staffs confirmed that this had never occurred, the inspector noted that the nursing staff had not been given sufficient instruction in proper methods for handling brachytherapy sources and were ill prepared to complete this task. Licensee representatives were alerted to the fact that the instructions in the form appeared inappropriate given the level of training provided to the nursing staff.

The authorized users all stated that they remembered having been provided with a copy of the program (or thought they had received a copy); however, the authorized users stated that they had received no training in the program themselves. Authorized users also stated that they found the system of three forms to be confusing and were initially uncertain as to what form was to be used as a written directive. In addition, two of the authorized users emphasized that they found it difficult to specify treatments in the manner prescribed by the QM program because they typically planned a treatment according to a desired absorbed radiation dose rather than in terms of source strength and implantation period alone. As a result, they relied upon both the forms prescribed under the QM program and the final treatment plan to serve as a record of the prescribed tumor dose.

Likewise, the consulting physicists working for both groups of physicians stated that they had not received any training in the QM program. In fact, they were uncertain as to whether they had received copies of the program prior to the recent investigations. As noted elsewhere in this report, these

physicists were responsible for treatment planning and assisting in source loading.

The issues involving participation of individuals responsible for performing brachytherapy treatments in the development of the QM program and the lack of training provided to physicists who were chiefly responsible for developing treatment plans were identified as significant concerns to licensee management. In particular, the inspector noted that both groups of physicians and consulting physicists had very different methods for planning brachytherapy treatments and that the program failed to take into consideration some unique aspects of treatment planning and information handling associated with one group of physicians. The latter issue involves physician Group 2 which because of the geographic location of treatment planning systems used by this group, had employed the use of fax machines to transmit data from simulation radiographs as well as treatment plan information. SVHHC's QM program did not address verification of the accuracy of this method of information exchange at all.

In addition, the inspector noted that as a result of SVHHC's failure to involve the authorized users and physicists in development of the program and in training, the authorized users and physicists did not fully appreciate the requirements specified in Form C and had not complied with that portion of the program.

Two apparent violations associated with the issues discussed above were identified. The first involved the failure to train all individuals working under the supervision of the licensee's authorized users in the provisions of the QM program. The failure to train the physicists responsible for treatment planning in the provisions of the QM program was identified as an apparent violation of 10 CFR 35.25(a)(1) which specifies, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user must instruct the supervised individual in the licensee's written quality management program (Apparent Violation 030-02396/9401-01).

The second apparent violation involved three examples of failures of individuals working under the supervision of authorized users to comply with the provisions of SVHHC's QM program for (1) testing the accuracy of computer algorithms for calculating dose rates, (2) verifying the accuracy of source localization in final treatment plans, and (3) verifying the patient's identity by more than one method. These issues are described more fully below.

As noted above, SVHHC's QM program specifies that digital and manual computers used for calculating radiation dose rates must be tested for accuracy and that such tests will include verification of the dose rate calculated from single sources at several distances and from combinations of single sources to determine if the summation of dose rates is performed correctly. Two of the three computer systems used by SVHHC's authorized users had been tested for accuracy (these tests were completed for an A.R.S. system and the Theraplan

system). However, the tests only included dose tables for single sources rather than for combinations of sources as specified in SVHHC's QM program. The only instance in which dose rates for combinations of sources were verified was for treatment plans developed on the Theraplan system. As discussed in Sections 2 and 3, these checks were inadequate to determine the accuracy of computer algorithms used by the Theraplan system. In addition, the third system, a C.M.S. treatment planning system, had not been tested for accuracy.

The second example involved a failure to perform the data entry and source position verification tests described in Form C of the QM program. First, Form C which specifies that data input to treatment planning systems must be verified for accuracy. Through review of the brachytherapy treatments performed since the inception of the QM program and interviews with individuals involved in treatment planning, the inspector determined that this verification was often not performed. Secondly, Form C specifies that verification of the correct transfer of source position from the x-ray film (simulation radiographs) to the treatment planning system will be performed by a direct spatial comparison between the AP (anterior-posterior) and lateral radiographs and the AP and lateral projection of the computer-derived isodose plots. Further, the test requires that the isodose plot be magnified to the identical magnification of the radiographs and that the radiographs be overlaid so the source position in the radiograph may be compared with the representative line in the isodose plot. Through interviews with SVHHC's authorized users and consulting physicists, the inspector determined that physician Group 1 had done this on possibly two occasions and that physician Group 2 had not performed the check for any treatment done by authorized users in Group 2. Based on information provided by the physicians and physicists, it appeared that it was merely by chance that physician Group 1 had conducted the check because all individuals interviewed stated that they were unaware of this requirement.

The third example involved at least three cases in which the patient's identity was not verified by more than one method. Two of the treatments were performed in May 1993, and the third was performed in December 1993. (It should be noted that these were cases in which records indicated that the methods used to verify the patient's identity were not independent. In some cases, the staff had not recorded, nor could they determine, the specific methods used to verify the patient's identity.) This problem appeared to be the result of SVHHC's failure to either provide sufficient instruction in the QM program or to develop specific procedures to instruct individuals regarding acceptable methods for verifying a patient's identity.

SVHHC's QM program provided no instruction in this task and as a result, individuals had relied upon various methods for verifying a patient's identity. This task was usually completed by the technical staff who relied first upon asking the patient to confirm his or her name. As a second method, the staff relied upon whatever information was available to them. In many instances, the patient was awake and had a driver's license or other photographic form of identification available for review. However, in at

least three cases, no form of identification was available beyond the patient's wrist band which was received during the admission process. In reviewing this process further, the inspector found that the staff had never queried the admissions staff as to what information was required for review prior to the patient receiving a wrist band (the band only displayed the patient's name, physician, and hospital identification). The staff, upon questioning, determined that the only information that the admissions staff required was for the patient to verbally state his or her name during the admission process. According to the staff, it was not necessary for the patient to provide the admissions staff with any other form of identification (i.e., insurance identification, social security number, etc.) in order to get a wrist band. Based upon this information, it appeared that the staff had only relied upon verifying the same information twice in some cases rather than verifying two independent sets of information.

Failures to perform accuracy checks, data entry and source position verification checks, and patient verification checks by more than one method were identified as examples of an apparent violation of 10 CFR 35.25(a)(2) which specifies, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user must require the supervised individual to follow the QM procedures established by the licensee (Apparent Violation 030-02396/9401-02).

The apparent violations discussed above are notable because some of the issues involved checks which are designed to identify potential errors prior to treatment. In particular, the failure to verify accuracy of computer algorithms for one or more treatment planning systems or to ensure that treatment plan verification checks were performed correctly was of concern because an error which occurred in checking computer-generated dose rate tables was identified the root cause of six misadministrations. In addition, the inspector was informed by one physics consultant that routine verification checks of dose rate tables were not performed unless the isodose plots "appeared unusual or incorrect." The inspector noted to licensee management that a visual check of isodose curves or of dose tables is generally not sufficient to detect errors in calculations.

The inspector also discussed concerns with licensee management regarding the fact that provisions of the QM program relating to verification of computer algorithms were too vague and failed to inform the users of the benchmarks to be used for comparison (i.e., what dose rate tables should be used for comparison). Also, SVHHC failed to ensure that such data was submitted to SVHHC staff for review. The consultant who developed the program did note that both groups of physics consultants had submitted dose tables to him shortly after the QM program was implemented; however, he had not retained the data and apparently did not note that the tables submitted by the consultants did not meet the requirements specified in the QM program.

In addition to the concerns noted above, the inspector noted that SVHHC had failed to consider in its QM program the fact that one group of physicians had transmitted source position information via fax machine. This process

involved a physician documenting on paper, by tracing from a radiograph, the position of brachytherapy sources along with some marking to indicate the magnification factor of the radiographs then transmitting the data to a remote location for use in treatment planning. The inspector noted that this process is subject to errors, not only from the manual process of tracing but also from changes in magnification which could occur during data transmission. In this particular case, the provisions of Form C of the licensee's QM program were never met because the individual who completed the treatment plans never had access to the simulation radiographs.

In addition to oversights regarding the provisions of SVHHC's QM program, the inspector also noted that the QM program did not require that treatment plans be retained by SVHHC. In fact, the inspector identified several cases in which treatment plans had not been maintained by SVHHC and for which it was impossible to verify whether the correct information had been used to develop the treatment plan. This was identified as a concern because the authorized users often failed to record the serial number of the sources used for an implant (they instead recorded a nominal source strength), and the sources possessed by SVHHC varied by as much as 1-2 millicuries for some nominal source strengths. Thus, the inspector and licensee representatives were unable in some cases to verify that the correct source activity had been used to calculate dose rates for the purposes of treatment planning.

These issues were highlighted to licensee management as items warranting further review in order to ensure that sufficient controls were implemented to prevent errors in treatment.

The inspector also identified several areas in which the licensee's QM program had failed to meet the objectives of 10 CFR 35.32, NRC's QM Rule. The first issue involved the authorized users' adherence to the requirement to complete a written directive prior to the completion of a brachytherapy treatment. Although SVHHC's QM program does require the use of two forms which, with one exception, meet the information requirements specified in 10 CFR 35.2 for a written directive for brachytherapy treatments, the authorized users had not always completed the forms in their entirety prior to the completion of each brachytherapy treatment. Specifically, eight cases were identified in which Form A, "Directive for the Administration of Brachytherapy Isotopes," and Form B, which requires documentation of the information required by NRC in a written directive, were either incomplete, incorrect, or had been completed after brachytherapy sources were explanted by an individual other than the authorized user who prescribed the treatment. These treatments were performed in September and November 1992, and January, March, May, August, November and December 1993. The treatments involved the use of cesium-137, iridium-192, and iodine-125 sources. In addition, neither Form A nor Form B required the authorized users to specify the treatment site. As a result, none of the written directives contained this information.

In three cases, written directives were not signed by the authorized user and in one of these cases, the authorized users' name was affixed to the record by another individual. Also, three cases were identified in which portions of

the written directive were modified by SVHHC staff members after treatment was completed. The modifications made to the written directives involved correcting the source strengths to represent the actual sources used and adding information such as the exposure period.

In discussing these cases with SVHHC staff, the staff indicated that some of the problems had been identified during the reviews conducted by the RSC; however, records of the QM program reviews conducted during RSC meetings were insufficient to determine how many or which errors had been caught by RSC members. The staff confirmed that they had annotated and modified the written directives after treatment was completed, but stated that this was done because the committee members believed that the correct information should be entered into the record for future use. One staff member also acknowledged that certain committee members had been made aware that a technologist signed an authorized user's name to a written directive and noted that the employee had been counseled after this discovery. The staff member explained that the technologist had only intended to ensure that the correct physician's name was on the form and that there was no intent on the technologist's behalf to make it appear that the physician had signed the form prior to treatment.

The failure to include all required information in written directives was identified as an apparent violation of 10 CFR 35.32(a) which specifies, in part, that each licensee must establish and maintain a written QM program that includes policies and procedures to meet the objective that prior to administration, a written directive is prepared for any brachytherapy radiation dose. 10 CFR 35.2 defines a written directive for brachytherapy as an order in writing for a specific patient, dated and signed by an authorized user prior to administration of radiation which contains, prior to implantation, the radioisotope, number of sources, and source strengths, and after implantation but prior to completion of the procedure, the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose). The failure of authorized users to sign written directives, to specify the source strength and exposure time, and to specify the treatment sight in written directives was identified as an apparent violation of 10 CFR 35.32(a) (Apparent Violation 030-02396/9401-03).

The second area in which SVHHC's QM program failed to meet an objective specified in NRC's QM Rule involved the treatment planning process. Specifically, although SVHHC's QM program specified two types of checks for verifying the accuracy of data input for computerized treatment plans, these checks proved inadequate to ensure that each administration of radiation was in accordance with the written directive and the authorized user's intended tumor dose. The failure to verify the accuracy of computer-generated dose tables and to perform adequate independent checks of computer-generated treatment plans contributed to six misadministrations that went unrecognized for some period of time. The treatments were performed in October and November 1992, and January, March, and October 1993. Based upon the results of the inspection, the licensee's QM program was found inadequate to ensure that the intended radiation dose was administered in each case.

10 CFR 35.32(a)(4) specifies, in part, that a licensee must establish and maintain a written QM program that includes policies and procedures to meet the objective that each administration of radiation is in accordance with the applicable written directive. The failure to include policies or procedures to ensure that each administration of radiation was in accordance with the radiation dose specified in the authorized user's written directive was identified as an apparent violation of 10 CFR 35.32(a)(4) (Apparent Violation 030-02396/9401-04).

One other item of concern was identified regarding the level of detail and scope of QM program reviews performed by the RSC. The policy incorporated in the licensee's QM program was largely focused on a review of the three forms described in the program. The reviews conducted by the RSC did not include the treatment plan in the majority of cases because the RSC did not always have a copy of the plan available, nor did the QM program specify that treatment plans should be retained with the patient's records. As a result, the records reviewed by the RSC did not constitute a full record of the treatment administered to each patient. The RSC had not reviewed the final plan of treatment against the written directive to ensure that the plan was in accordance with the written directive and was unable to determine whether the intended absorbed dose was administered to the prescribed treatment site. In short, the reviews were limited to verifying that all required data was included in each form. In addition, the reviews did not include an assessment of the processes used by SVHHC's authorized users and physicists for treatment planning. Thus, the reviews lacked the level of detail and depth required to identify an error in treatment.

In summary, two apparent violations, with multiple examples, were identified involving (1) a failure to train individuals in the provisions of the QM program and (2) a failure to require that individuals working under the supervision of authorized users comply with the provisions of the QM program. In addition, two apparent violations were identified involving a failure to establish and maintain a QM program that met the objectives of the QM Rule for preparing written directives and ensuring that each dose of radiation from byproduct material was in accordance with an authorized users' written directive. A concern was also identified regarding the level of detail of the QM program reviews.

5 BRACHYTHERAPY PROGRAM OVERSIGHT (87100)

Based upon interviews of SVHHC staff members, authorized user physicians, and the licensee's consulting physicists, several concerns were identified regarding the oversight which licensee management and the RSO had provided for SVHHC's brachytherapy program. These concerns involved weaknesses in communications between the various individuals who participated in performing and planning bracnytherapy procedures as well as a failure of the RSO to conduct reviews of activities associated with the brachytherapy program, including the six misadministrations. One apparent violation involving the RSO's failure to conduct an investigation of the six misadministrations was identified. In addition, three apparent violations related to records of

radiation surveys associated with brachytherapy treatments and brachytherapy source usage and inventory records were identified. The apparent violations and other concerns identified by the inspector are discussed below.

5.1 Communications

Almost unanimously, the authorized users and physicists involved in brachytherapy procedures at SVHHC noted that they had not been provided adequate opportunity to participate in the development of SVHHC's QM program. Concerns expressed regarding this issue were primarily focused on issues relating to the physicists' and authorized users' ability to comply with the program and the authorized users' concern that the forms required for use under the program were either confusing or were not in accordance with their preferred method for prescribing brachytherapy treatments. These issues appeared to be related to communication problems between some of the individuals involved in this program.

SVHHC staff also discussed some communication difficulties, although it appeared that the staff and the authorized users had been working to resolve these issues. These issues were primarily focused on problems associated with scheduling patients for brachytherapy treatments and the fact that in some cases, the technical staff had very little notice regarding when sources were to be implanted which made it difficult for them to ensure that a staff member would be available to perform the required radiation surveys.

The most notable communication problem appeared to involve the relationships established between the hospital and authorized users and consulting physicists. Although the specific reasons were not fully discussed during the inspection, SVHHC representatives expressed concerns that they were unable to review certain information maintained by the consulting physicists or the physicists' methods for performing treatment planning. In addition, the staff had not visited with the consulting physicists and the inspector found that the staff was unaware of some aspects of the treatment planning programs maintained by the authorized users. In some cases the inspector identified reluctance on the part of the physics consultants to permit SVHHC to review their treatment planning systems and processes; however, in other cases, the physicists appeared receptive to further involvement of the SVHHC staff.

Overall, communication problems expressed by various individuals to the inspector appeared to have resulted in lapses of communication among the various individuals involved in brachytherapy activities and reluctance of individuals to share information.

5.2 Oversight Provided by the RSO

Through discussions with the RSO, the inspector identified a number of concerns regarding the oversight provided by him for the brachytherapy program. Specifically, the RSO acknowledged that he had not routinely reviewed brachytherapy activities and had relied upon the technical staff to bring problems to his attention. However, the inspector noted that the

technical staff did not have full access to information necessary to perform adequate program reviews and had not been specifically trained in brachytherapy procedures. The technical staff had done a satisfactory job in performing radiation surveys associated with brachytherapy treatments, but they were not prepared to perform program reviews of sufficient detail to identify errors in treatment or problems in the treatment delivery process.

The RSO, who was primarily involved in diagnostic and interventional radiology procedure, also acknowledged that he did not have sufficient experience to review treatment plans to determine whether they were in accordance with written directives and had relied upon the consulting physicists to perform such checks on their own without further review by him. Based upon discussions with the RSO, it appeared that he had largely relied upon others to ensure that the brachytherapy activities for which they were responsible were carried out correctly and in accordance with the licensee's and NRC's requirements, and the only review of brachytherapy activities in which the RSO had routinely participated were the document reviews conducted during the RSC meetings.

The inspector discussed with the RSO her concern that the RSO had not participated in the investigations of the misadministrations. The RSO noted that he was present during the initial telephonic notification provided to NRC, and that he was aware of the variance in the radiation doses received by the patients versus the physicians' intended tumor doses. However, the RSO acknowledged that as of April 6, 1994, he was not aware of the actual doses received by the six patients associated with the misadministrations. The RSO also acknowledged to the inspector that he had not personally participated in the investigation nor had he reviewed the investigation findings with the consulting physicists and authorized users who conducted the investigation. The failure of the RSO to investigate six misadministrations, or to review investigation the findings, was identified as an apparent violation of 10 CFR 35.21(b)(1) which specifies, in part, that the RSO will investigate misadministrations (Apparent Violation 030-02396/9401-05).

5.3 Records Maintained for Brachytherapy Treatments

In reviewing the various records maintained for brachytherapy treatments, the inspector identified several issues warranting further review by the licensee. The most notable issues involved maintenance of records documenting brachytherapy treatments as discussed in Sections 3 and 4 of this report. However, the inspector also identified three apparent violations involving other records maintained to document activities associated with brachytherapy treatments.

The first issue involved records of surveys conducted following implantation and explantation of brachytherapy sources. The technical staff had completed the majority of surveys performed of the patient, the patient's room and surrounding areas after brachytherapy sources were implanted, although on occasion sources were implanted during the evening hours and the authorized users had conducted the surveys. Generally, the surveys appeared to have

included all areas surrounding the patient's room and based upon interviews with the staff and a review of the survey records, it appeared that the technical staff had restricted the surrounding areas appropriately when required. However, the records of these surveys maintained by SVHHC did not include all required information. Specifically, the staff had maintained records of each survey which included the time and date of the survey, the points and areas surveyed, the measured dose rates, and the initials of the individual who conducted the survey. However, the records did not include information regarding the instrument used to conduct the survey. This was identified as an apparent violation of 10 CFR 35.415(a)(4) which requires, in part, that records of surveys conducted to demonstrate compliance with this section be retained for a period of 3 years and that the record contain the time and date of the survey, a plan of the area surveyed or a list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey (Apparent Violation 030-02396/9401-06).

Likewise, the licensee had retained records of patient surveys completed after brachytherapy sources were removed, but these records were found to lack some information required by NRC. Specifically, licensee representatives had only recorded a dose rate (as measured at a distance of approximately 1 meter) and the date, time, and initials of the individual who completed the survey. There was no information recorded regarding the instrument used to conduct the survey. This was identified as an apparent violation of 10 CFR 35.404(b) which requires, in part, that a records of surveys conducted in accordance with 10 CFR 35.404(a) must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour, the survey instrument used, and the initials of the individual who made the survey (Apparent Violation 030-02396/9401-07).

The inspector also noted that the licensee's records of brachytherapy source usage and inventory were incomplete in that they did not account for the full inventory of sources, including the number and activity of the sources removed/returned from storage as well as the number and activity of those remaining in storage. The records only contained information on the sources removed from storage, their color coding, and the initials or name of the individual who removed the sources. Thus, neither the individuals who used the sources or those who monitored this activity were able to account for the full inventory of brachytherapy sources at any given time without conducting a physical inventory. In addition, the licensee had not made a record of the names of individuals permitted to handle brachytherapy sources at SVHHC. These findings were identified as an apparent violation of 10 CFR 35.406(b) which requires, in part, that a licensee make a record of brachytherapy source use which must include: (1) the names of individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, as well as the number and activity of sources remaining in storage after source removal; and (3) the number and activity of sources returned to storage, along with the number and activity of sources in storage following return of sources (Apparent Violation 030-02396/9401-08).

None of the above noted apparent violations had been identified by the RSO. Although the RSO had reviewed records of area and patient surveys during the quarterly reviews of the licensee's QM program, he failed to note that all required information was not documented. The RSO had not reviewed the source inventory records during periodic program reviews and had instead relied upon one of the licensee's consultants to review the aforementioned records. The failure of the RSO to conduct program reviews of sufficient detail to identify these oversights was identified as a concern relating to the RSO's oversight of the brachytherapy program.

ATTACHMENT 1

1 Persons Contacted

Wiley Bland, M.D., Radiation Safety Officer
Thomas Cherewick, M.S., Physics Consultant
Fred Deigert, M.D., Radiation Oncologist
Mark Dion, M.D., Radiation Oncologist
Mark Edwards, Ph.D., Physics Consultant
Gordy Fuchs, Manager, Radiology
Michael T. Gillin, Ph.D., Physics Consultant
Ross Kachaniwsky, Manager, Quality Assurance, Theratronics Ltd.
Frank Lamm, M.D., Radiation Oncologist
Edward Martell, Vice President, Quality Assurance & Regulatory Affairs, Theratronics Ltd.
Greg Murphy, Attorney for St. Vincent Hospital and Health Center
James Paquette, President, St. Vincent Hospital and Health Center
William Powers, M.D., Radiation Oncologist (Consultant)
Jim Robbins, Chief Technologist, Nuclear Medicine
David Switzer, M.S., Physics Consultant
Lionel Tapia, M.D, Vice President of Medical Affairs
John Terry, M.D., Radiation Oncologist
Rod Wimmer, M.S., Physics Consultant

Other staff members working at St. Vincent Hospital and Health Center were also interviewed.

2 Exit Briefing

On April 1, 1994, a public interim exit briefing was conducted in Billings, Montana, to review the findings of the initial segment of the inspection. A telephonic exit briefing was conducted on April 19, 1994, with Dr. Lionel Tapia and Mr. Greg Murphy of St. Vincent Hospital and Health Center's staff to review the inspection findings as presented in this report.

APPENDIX C

PROPOSED ENFORCEMENT CONFERENCE AGENDA
ST. VINCENT HOSPITAL AND HEALTH CENTER

June 28, 1994 1:15 p.m. (CDT)

I. INTRODUCTION AND PURPOSE	L. J. CALLAN
II. EXPLANATION OF ENFORCEMENT POLICY	G. F. SANBORN
III. NRC DISCUSSION OF APPARENT VIOLATIONS	C. L. CAIN L. L. KASNER
IV. LICENSEE COMMENTS AND RESPONSE/CORRECTIVE ACTION	J. PAQUETTE L. TAPIA
V. CLOSING COMMENTS	S. J. COLLINS

ATTACHMENT 2

Saint Vincent Hospital and Health Center

January 20, 1992

United States Nuclear Regulatory Commission
611 Ryan Plaza Suite 1000
Arlington, Texas 76001

RE: License Number 25-07553-01

Gentlemen:

Saint Vincent Hospital and Health Center has included in its Policy and Procedures Manual additions necessary to reflect the NRC requirements for conducting Brachytherapy and Radioiodine therapy. A copy of those Policy and Procedures is included with this letter.

If there are any additional questions please do not hesitate to contact us.

Sincerely,

James T. Paquette
President

Post Office Box 35200
Billings, Montana 59107-5200
406-657-7000

We touch your life.

POLICY AND PROCEDURES FOR I-125 AND I-131

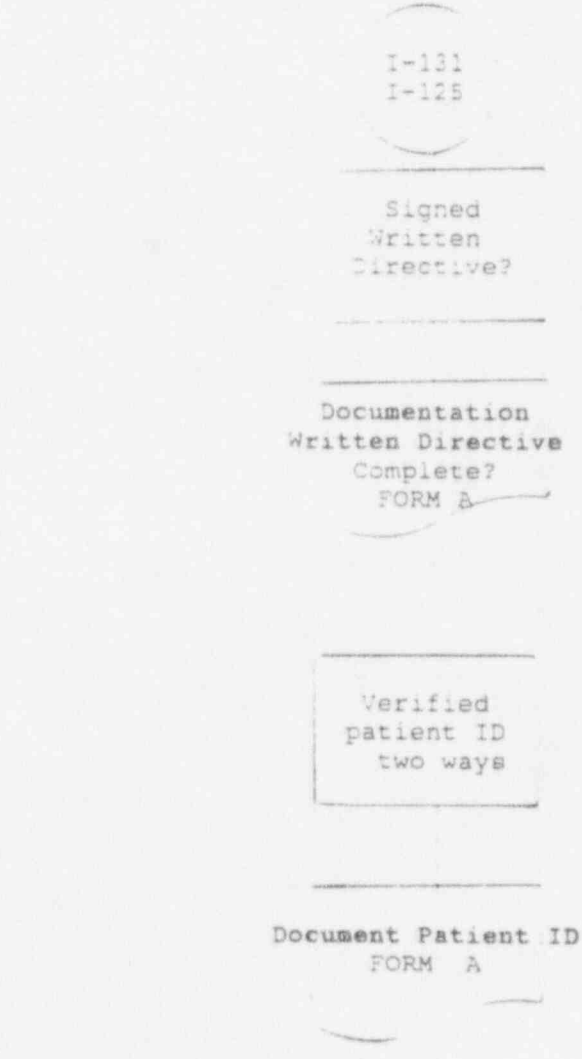
POLICY:

The Nuclear Medicine Department requires before the human use of either radioactive I-125 or I-131, in quantities greater than 30 microcuries, that the Authorized User must provide a signed Written Directive for the use of these isotope of Iodine. Additionally, the patient's identity must be verified by two separate methods as well as the type, quantity and route of administration of the radioactive material.

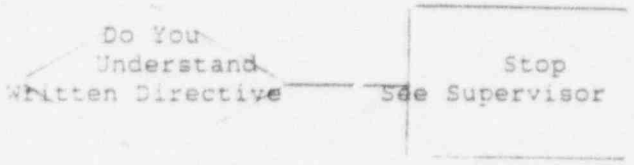
PROCEDURE

The Form A accompanying this document represents the information that must be recorded for each Radioiodine administration. However, it is not necessary to use these forms as long as all the information requested on these forms is recorded and made available for review.

PROCEDURAL FLOW CHART FOR RADIOIODINE PATIENTS



PROCEDURE FOR I-125/I-131



Record
Material Verification
FORM A

Document
Dose Calibrator
Reading
FORM A

Administer
Material

Record in patient chart:
Radioisotope
Quantity
Route

DIRECTIVE FOR THE AMDINISTRATION OF
I-125 OR I-131

Requesting Physician: _____
Date: _____

Patients Name: _____
Address: _____
Age: _____
Birthdate: _____
SSN: _____

Iodine-131

The Nuclear Medcine Department is directed to administer to the above identified patient _____ (amount/activity) of _____ (isotope).

Route of administration: _____
(oral/intravenous)

Iodine-125

The Nuclear Medcine Department is directed to administer to the above identified patient _____ (amount/activity) of _____ (isotope).

Route of administration: _____
(oral/intravenous)

_____
Signature

This form is required for each administration of I-125 or I-131.

FORM A

Administration of I-131/I-125
(Doses greater than 30 **microcuries**)

NOTE: Circle yes or no, fill in blanks, and sign as required. If you do not understand this procedure, then contact Dr. J. Anderson or Mr. J. Robbins and do not proceed until you do understand.

1. Verify that a **Written** Directive (or prescription) has been made for this administration.

_____ Yes _____ NO

2. Verify that the patients name (identity) is the same as on the Written Directive as follows (circle as many as possible):

a) Patient states his/her name - Yes/No

b) Verify name and compare photograph on patients drivers license - Yes/No

c) If inpatient, verify name on chart - Yes/No

d) If inpatient, verify name on identification bracelet on wrist - Yes/No

3. If patient is female in childbearing age group, then have proof of non-pregnancy by:

a) A negative pregnancy test - Yes/No
c) Also, patient sign appropriate permits - Yes/No

4. All patients must sign general permit form after physician has explained the nature of the administration to them - Yes/No

5. I _____ have checked the dose of radionuclide _____ in the dose calibrator on _____/92 _____ am/pm _____ mCi/uCi.

6. I _____ have recorded the dose and the patients name in the appropriate log books in the department - Yes/No.

7. I _____ have witnessed the administration of I-131/I-125 of _____ mCi/uCi at _____am/pm on _____/92.

BRACHYTHERAPY POLICY

Treatment Planning Computer

Any digital or manual computer used for calculating radiation dose rates caused by radioactive sources shall be tested for accuracy. Such testing shall include the dose rate from single sources at serval distances and combinations of single sources to determine if the summation of doserates arising from single sources is preformed correctly.

Review of QM Program

The Quality Management Program established by the enclosed procedures shall be reviewed at every Radiation Safety Committee. Such reviews shall include but not be limited to a review of all records of implants and Radioiodine administration during the previous quarter. The records shall be reviewed for completeness and consistency.

BRACHYTHERAPY PROCEDURES

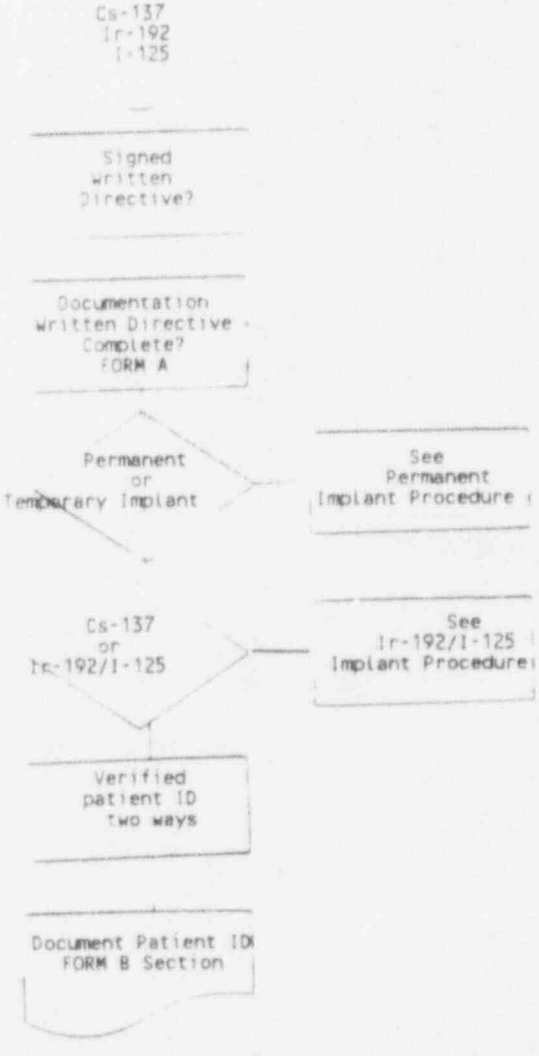
Policy and Procedures for Brachytherapy Application

Policy

The Nuclear Medicine Department requires a **Written Directive** signed by the Authorized user prior to the Human Use of Cs-137, Ir-192 and I-125 and other isotopes that may be added to the Brachytherapy inventory. Concomitantly, it is further required that the patients identity, as well as the type, activity, and numbers of radioactive sources be verified prior to insertion of the radioactive material. Radiographs are to be used to determine source position for each patient and all calculations be checked before twenty-five percent of the treatment interval has elapsed.

The forms A, B, and C that accompany this document represent all the information that must be recorded for each brachytherapy implant. However it is not necessary to use these forms as long as all the information requested on these forms is recorded and made available for review.

PROCEDURAL FLOW CHART FOR BRACHYTHERAPY IMPLANTS



PROCEDURES FOR BRACHYTHERAPY

BRACHYTHERAPY PROCEDURES

Temporary Implant
Ir-192/I-125

Temporary
Implant
Ir-192/I-125

Document
Patient ID
FORM B Section 1

Understand
Written Directive

Stop
See Supervisor

Radiograph
Implant

Record
Material Verification
FORM B Section 2

Calculate
Isodose
Distribution

Record in Chart
Radioisotope,
Activity
Number of Sources

Check Calculations
Record information
FORM C

BRACHYTHERAPY PROCEDURES

Temporary Implant
Ir-192/I-125

Temporary
Implant
Ir-192/I-125

Document
Patient ID
FORM B Section 1

Understand
Written Directive — Stop
See Supervisor

Radiograph
Implant

Record
Material Verification
FORM B Section 2

Calculate
Isodose
Distribution

Record in Chart
Radioisotope,
Activity
Number of Sources

Check Calculations
Record information
FORM C

FORM A

DIRECTIVE FOR THE ADMINISTRATION OF
BRACHYTHERAPY ISOTOPES

Cs-137

Requesting Physician: _____
Date: _____

Patients Name: _____
Address: _____

Cs-137

The Nuclear Medicine Department is directed to administer to the above named patient _____ (# of sources) of **Cs-137**. The source distribution has been determined by computerized treatment planning and is as follows:

Tandem: ____ Sources

1st source ____ mg

2nd source ____ mg

3rd source ____ mg

4th source ____ mg

Ovoids:

Patients Left _____ mg

Patients Right _____ mg

Total Activity _____ mg

_____ _____
Signature

FORM B

Section 1: PATIENT VERIFICATION

Cs-137

Technologist/Authorized User: _____
Date: _____
Time: _____

I have confirmed the identity of Mr./Ms. _____ by asking his/her name as given on the written directive. I have also identified the patient by a secondary method.

Section 2: RADIOACTIVE MATERIAL VERIFICATION

Technologist/Authorized User: _____
Date: _____
Time: _____

If you do not clearly understand the written directive or cannot successfully complete this form then seek guidance from the authorized user and report to your supervisor immediately.

I have read the Radiopharmacuetical directive signed by _____ and I understand that the patient is to receive a total of _____ Cs-137 sources. One source of ___ mg 226Ra eqv in (patients) right ovoid and one source of ____ mg in the (patients) left ovoid and _____ sources in the tandem. The tandem sources are loaded in the following manner:1-_____ mg; 2-_____ mg;3-_____ mg;4-_____mg (Convention-the 1st source in at the sealed end of the tandem).

Section 3: LOADING

Source Custodian:_____ Time: _____

I have loaded the sources in the following configuration and I have verified the source activity by observing and recording either the source serial number or its color code identifying its activity.

TANDEM
Written Directive: Source number 1-_____ mg;2-_____mg;3-_____mg;4-____mg
As loaded: Source number 1-_____;2-_____;3-_____;4-_____
(Serial number or source color coding)

OVOIDS
Written Directive: Source number Right ovoid-_____ mg;Left ovoid-_____mg
As loaded: Source number Right ovoid_____ Left ovoid-_____
(Serial number or source color coding)

Total number of 226Ra eqv mg _____ Treatment time ____ hrs

TOTAL mg-hrs OF TREATMENT _____ AUTHORIZED USER _____

FORM C

DOSE CALCULATIONS CHECK

Cs-137

Verification of data input to the computer system shall be achieved by recording on a separate sheet the data obtained from the Written Directive and the data taken from the computer printout specifying the details of the treatment plan (plan summary).

Patient Name: _____
Date: _____

Source strength from written directive.	Source strength from computer summary.
Tandem sources:	Tandem sources:
1-_____	1-_____
2-_____	2-_____
3-_____	3-_____
4-_____	4-_____
Ovoids:	Ovoids:
Rt-_____	Rt-_____
Lt-_____	Lt-_____

Source Position Verification

Verification of the correct transfer of source position from the x-ray film to the treatment planning computer shall be perfomred by a direct spatial comparison between the AP and Lateral x-ray films and the AP and Lateral projection of the computer derived isodose plots. The isodose plot shall be magnified to the identical magnification of the x-ray film and then the x-ray film overlaid so the source position defined by the opacity of the dummy source overlays the line representation of the computer isodose plot.

It is understood that there is a digitizer error from the initial source entry that will be magnified by the magnification of the isodose plot. Therfore it is acceptable if there is less than a 2 mm deviation bewteen the postion indicated by the isodose plot and the postion of the opacity representing the dummy source position.

FORM A

DIRECTIVE FOR THE AMDINISTRATION OF
BRACHYTHERAPY ISOTOPES

Ir-192

Requesting Physician: _____
Date: _____

Patients Name: _____
Address: _____

Ir-192

The Radiation Oncology Department is directed to administer to the above named patient _____ (# of sources) of **Ir-192** haveing an activity per soure of ____ mCi for a total activity of ____ mCi/mg.

Frequently the number, spacial location and total activity for Ir-192 implants is determined at the time of surgery. It may necessary to use the oral directive for the use of this isotope. The authorized user shall complete this form no later than 24 hours following the source insertion

The original therapuetic aproach was modified at surgery and the patient recieved ____ sources of _____ mCi per source for a total activity of ____ millcuries.

FORM B

PATIENT VERIFICATION

Ir-192

Section 1: Patient Verification

Technologist/Autorized User: _____
Date: _____
Time: _____

I have confirmed the identity of Mr./Ms. _____ by asking his/her name as given on the written directive. I have confirmed the patients by second method.

Section 2: Radioactive Material Verification

RADIOACTIVE MATERIAL VERIFICATION

Technologist/Authorized User: _____
Date: _____
Time: _____

If you do not clearly understand the written directive or canot successfully complete this form then seek guideance from the authorized user and report to your supervisior immediately.

I have read the Radiopharmacuetical Directive signed by _____ and I understand that the patient is to recieve a total of _____ Ir192 sources. Each source is _____ mCi in strength.

Source Custodian:_____ Time: _____

Frequently the number, spacial location and total activity for Ir-192 implants is determined at the time of surgery. It may necessary to use the oral directive for the use of this isotope. The authorized user shall complete this form no later than 24 hours following the source insertion

The original therapuetic aproach was modified at surgery and the patient recieved ____ sources of _____ mCi per source for a total activity of ____ millcuries.

FORM C

DOSE CALCULATIONS CHECK

Ir-192

Verification of data input to the computer system shall be achieved by recording on a separate sheet the data obtained from the Written Directive and the data taken from the computer printout specifying the details of the treatment plan (plan summary).

Patient Name: _____
Date: _____

Number of sources from written directive.	Number of sources from computer summary.
_____	_____
Source activity from written directive	Source activity from computer summary
_____	_____

Source Position Verification

Verification of the correct transfer of source position from the x-ray film to the treatment planning computer shall be performed by a direct spatial comparison between the AP and Lateral x-ray films and the AP and Lateral projection of the computer derived isodose plots. The isodose plot shall be magnified to the identical magnification of the x-ray film and then the x-ray film overlaid so the source position defined by the opacity of the source overlays the line representation of the computer isodose plot.

It is understood that there is a digitizer error from the initial source entry that will be magnified by the magnification of the isodose plot. Therefor it is acceptable if there is less than a 2 mm deviation between the position indicated by the isodose plot and the position of the opacity representing the source position.

_____
Reviewer

FORM A

DIRECTIVE FOR THE ADMINISTRATION OF
BRACHYTHERAPY ISOTOPES

I-125

Requesting Physician: _____
Date: _____

Patients Name: _____
Address: _____

I-125

The Nuclear Medicine Department is directed to administer to the above name patient _____ (# of sources) of **I-125** having an activity per source of ____ mCi for a total activity of ____ millicuries.

Frequently the number, spatial location and total activity for I-125 seeds are determined at the time of surgery. It may necessary to use the oral directive for the use of this isotope. The authorized user shall complete this form no later than 24 hours following the implant procedure.

Documentation of the Oral Directive

The original therapeutic approach was modified at surgery and the patient received ____ sources of _____ mCi per source for a total activity of ____ millicuries.

FORM B

PATIENT VERIFICATION

I-125

Section 1: Patient Verification

Technologist/Autorized User: _____
Date: _____
Time: _____

I have confirmed the identity of Mr./Ms. _____ by asking his/her name as given on the written directive. I have confirmed the patients identity through a second method.

RADIOACTIVE MATERIAL VERIFICATION

Section 2: Radioactive Material Verification

Technologist/Authorized User: _____
Date: _____
Time: _____

If you do not clearly understand the written directive or canot successfully complete this form then seek guideance from the authorized user and report to your supervisior immediately.

I have read the Radiopharmacuetical Directive signed by _____ and I understand that the patient is to recieve a total of _____ I-125 sources. Each source is _____ mCi in strength.

Source Custodian:_____ Time: _____

Frequently the number, spacial location and total activity for I-125 implants is determined at the time of surgery. It may necessary to use the oral directive for the use of this isotope. The authorized user shall complete this form no later than 24 hours following the source insertion

The original therapuetic aproach was modified at surgery and the patient recieved ____ sources of _____ mCi per source for a total activity of ____ millcuries.

FORM C

DOSE CALCULATIONS CHECK

I-125

Verification of data input to the computer system shall be achieved by recording on a separate sheet the data obtained from the Written Directive and the data taken from the computer printout specifying the details of the treatment plan (plan summary).

Patient Name: _____
Date: _____

Number of sources from written directive.	Number of sources from computer summary.
_____	_____
Source activity from written directive (per source)	Source activity from computer summary (per source)
_____	_____

Source Position Verification

Verification of the correct transfer of source position from the x-ray film to the treatment planning computer shall be perfomred by a direct spatial comparison between the AP and Lateral x-ray films and the AP and Lateral projection of the computer derived isodose plots. The isodose plot shall be magnified to the identical magnification of the x-ray film and then the x-ray film overlaid so the source position defined by the opacity of the source overlays the line representation of the computer isodose plot.

It is understood that there is a digitizer error from the initial source entry that will be magnified by the magnification of the isodose plot. Therfore it is acceptable if there is less than a 2 mm deviation bewteen the postion indicated by the isodose plot and the postion of the opacity representing the source position.

_____
Reviwer

APPENDIX D

I. Criteria For Selecting Open Enforcement Conferences

Enforcement conferences will not be open to the public if the enforcement action being contemplated—

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of an NRC Office of Investigations (OI) report; or

(4) Involves safeguards information, Privacy Act information, or other information which could be considered proprietary.

Enforcement conferences involving medical misadministrations or overexposures will be open assuming the conference can be conducted without disclosing the exposed individual's name. In addition, enforcement conferences will not be open to the public if the conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility. Finally, with the approval of the Executive Director for Operations, enforcement conferences will not be open to the public in special cases where good cause has been shown after balancing the benefit of public observation against the potential impact on the agency's enforcement action in a particular case.

The NRC will strive to conduct open enforcement conferences during the two-year trial program in accordance with the following three goals:

(1) Approximately 25 percent of all eligible enforcement conferences conducted by the NRC will be open for public observation;

(2) At least one open enforcement conference will be conducted in each of the regional offices; and

(3) Open enforcement conferences will be conducted with a variety of the types of licensees.

To avoid potential bias in the selection process and to attempt to meet the three goals stated above, every fourth eligible enforcement conference involving one of three categories of licensees will normally be open to the public during the trial program. However, in cases where there is an ongoing adjudicatory proceeding with one or more intervenors, enforcement conferences involving issues related to the subject matter of the ongoing adjudication may also be opened. For the purposes of this trial program, the three categories of licensees will be commercial operating reactors, hospitals, and other licensees, which will consist of the remaining types of licensees.

II. Announcing Open Enforcement Conferences

As soon as it is determined that an enforcement conference will be open to public observation, the NRC will orally notify the licensee that the enforcement conference will be open to public observation as part of the agency's trial program and send the licensee a copy of this *Federal Register* notice that outlines the program. Licensees will be asked to estimate the number of participants it will bring to the enforcement conference so that the NRC can schedule an appropriately sized conference room. The NRC will also notify appropriate State liaison officers that an enforcement conference has been scheduled and that it is open to public observation.

The NRC intends to announce open enforcement conferences to the public normally at least 10 working days in advance of the enforcement conference through the following mechanisms:

(1) Notices posted in the Public Document Room;

(2) Toll-free telephone messages; and

(3) Toll-free electronic bulletin board messages.

Pending establishment of the toll-free message systems, the public may call (301) 492–4732 to obtain a recording of upcoming open enforcement conferences. The NRC will issue another Federal Register notice after the toll-free message systems are established.

To assist the NRC in making appropriate arrangements to support public observation of enforcement conferences, individuals interested in attending a particular enforcement conference should notify the individual identified in the meeting notice announcing the open enforcement conference no later than five business days prior to the enforcement conference.

III. Conduct of Open Enforcement Conferences

In accordance with current practice, enforcement conferences will continue to normally be held at the NRC regional offices. Members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed.

Each regional office will continue to conduct the enforcement conference proceedings in accordance with regional practice. The enforcement conference will continue to be a meeting between the NRC and the licensee. While the enforcement conference is open for public observation, it is not open for public participation.

Persons attending open enforcement conferences are reminded that (1) the apparent violations discussed at open enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at open enforcement conferences or the lack thereof, are not intended to represent final determinations or beliefs.

In addition to providing comments on the agency's trial program in accordance with the guidance in this notice, persons attending open enforcement conferences will be provided an opportunity to submit written comments anonymously to the regional office. These comments will subsequently be forwarded to the Director of the Office of Enforcement for review and consideration.

Dated at Rockville, MD, this 7th day of July 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92–16233 Filed 7–9–92; 8:45 a.m.]

BILLING CODE 7590-01-M

Two-Year Trial Program for Conducting Open Enforcement Conferences; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing this policy statement on the implementation of a two-year trial program to allow selected enforcement conferences to be open to attendance by all members of the general public. This policy statement describes the two-year trial program and informs the public of how to get information on upcoming open enforcement conferences.

DATES: This trial program is effective on July 10, 1992, while comments on the program are being received. Submit comments on or before the completion of the trial program scheduled for July 11, 1992. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch.

Hand deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, MD between 7:45 a.m. to 4:15 p.m., Federal workdays.

Copies of comments may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-504-2741).

SUPPLEMENTARY INFORMATION:

Background

The NRC's current policy on enforcement conferences is addressed in Section V of the latest revision to the "General Statement of Policy and Procedure for Enforcement Actions," (Enforcement Policy) 10 CFR part 2, appendix C that was published on February 18, 1992 (57 FR 5791). The Enforcement Policy states that, "enforcement conferences will not normally be open to the public." However, the Commission has decided to implement a trial program to determine whether to maintain the current policy with regard to enforcement conferences or to adopt a new policy that would allow most enforcement conferences to be open to attendance by all members of the public.

Policy Statement

Position

The NRC is implementing a two-year trial program to allow public observation of selected enforcement conferences. The NRC will monitor the program and determine whether to establish a permanent policy for conducting open enforcement conferences based on an assessment of the following criteria:

(1) Whether the fact that the conference was open impacted the NRC's ability to conduct a meaningful conference and/or implement the NRC's enforcement program;

(2) Whether the open conference impacted the licensee's participation in the conference;

(3) Whether the NRC expended a significant amount of resources in making the conference public; and

(4) The extent of public interest in